FDA 510(k) Premarket Notification

# K234109 Ziehm Solo FD

**CLEARED**

Jan 26, 2024
30 days to decision

K234109 · Product code: **OWB** · Radiology
Source: https://www.510kdatabase.net/k234109/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Interventional Fluoroscopic X-ray System (OWB) |
| Date received | Dec 27, 2023 |
| Decision date | Jan 26, 2024 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Ziehm Imaging GmbH** |
| Location | Orlando, FL, US |
| Contact | Tsvetelina Milanova |
| 510(k) history | 18 submissions · 18 cleared · 2013-2025 |